

UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: ABBOTT LABORATORIES, ET AL., PRETERM INFANT NUTRITION PRODUCTS LIABILITY LITIGATION	MDL No 3026
This Document Relates to: <i>Inman v. Mead Johnson & Company, LLC</i> et al.,	Master Docket No. 1:22-cv-00071
Case No. 1:22-cv-03737	Hon. Rebecca R. Pallmeyer
Plaintiffs' Response to Defendants' Motion to Exclude Dr. Logan Spector (ECF No. 53)	

I. Introduction

Plaintiffs designated Dr. Logan Spector as their epidemiology expert to offer a general-causation opinion on whether cow's-milk-based formula (CMBF) causes NEC in premature and low-birth-weight infants. He opined that exposure to preterm infant formula can cause NEC, with greater exposure increasing the risk. No. 1:22-cv-03737, ECF No. 53-6 (Spector Rep.) at 3. Dr. Spector testified that he observed a causal association between exposure to CMBF and NEC as the amount of formula increased. ECF No. 616-3 (Spector Tr. Vol. 1) at 286:19–22; 348:10–349:3. He did not confine his opinion to infants who were never fed hydrolyzed formula.¹

According to the Court, “Dr. Spector’s broad analysis of studies exploring a range of different feeding mixtures applies across the diverse feeding methods in the MDL cases.” ECF No. 646 (Order), PageID #29131. Based on this observation, the Court specifically noted: “[Dr. Spector] has instead explained that although a precise triggering exposure may not be ascertainable, the epidemiological literature does establish that a dose-response relationship likely exists between [cow’s-milk-based formula] and NEC (more formula increases the likelihood of NEC).” ECF No. 646 (Order), PageID #29131.

Just as it did in the MDL-wide arguments the Court rejected months ago, Mead again attempts to exclude Dr. Spector’s opinions, alleging they do not rest on studies including infants whose

¹ A hydrolyzed product is a preterm infant formula in which the proteins in the formula are broken down to ease digestion. Hydrolyzed products have no impact on a preterm infant’s ability to digest either carbohydrates or fats—two macronutrients that pose serious impediments to preterm infant digestion. ECF No. 616-35 (Expert Rep. of Jennifer Sucre) at 32. Both products in this case were extensively hydrolyzed. The limited literature from extensively hydrolyzed products suggests they *may* mitigate the risk of NEC (although the results are not statistically significant). Derek Hang, Cheong Ng et al., *Protein hydrolysate versus standard formula for preterm formula*, Cochrane Database of Systematic Reviews (2019) attached to Declaration of Timothy J. Becker (Becker Decl.) as Exhibit A. Specifically, the results from Cochrane for extensively hydrolyzed products were approximately: RR: 2.14 (C.I. 0.19 – 23.09) rendering the results not significant. Becker Decl., Exhibit B. For standard and extensively hydrolyzed products the results were approximately: RR: 0.89 (C.I. 0.27 – 2.87). Becker Decl., Exhibit C. In other words, if either product played any role in D.W.’s outcome, they may have (arguably) mitigated against the risk of NEC. Yet, D.W. contracted NEC weeks after consuming the hydrolyzed products and while being exposed to formula.

circumstances match exactly those of the plaintiff. This issue was fully and fairly litigated and decided in May, but Mead seemingly intends to move in each individual case to exclude general-causation experts on the basis of each infant's unique circumstances and whether those exact circumstances were explicitly addressed in the experts' reports. It should be estopped from doing so.

And if Mead's argument that D.W.'s feeding pattern is so unique that no study Dr. Spector relied on could encompass his specific circumstances—he may be the only infant in this MDL with such a feeding pattern given the hydrolyzed products are not pre-term products—one could be forgiven for wondering why Mead chose a non-representative case for a bellwether trial. In any event, the inclusion of hydrolyzed products in D.W.'s feeding history is a red herring. Dr. Spector evaluated all studies that met his inclusion criteria irrespective of the “type” of formula the infant consumed. This approach is consistent with every defense expert in this case. Based on that analysis, Dr. Spector observed a causal association from exposure to formula.

There is no doubt that D.W. consumed substantial amounts of formula. Nonetheless, Mead argues that fact is somehow trumped by his nominal consumption of hydrolyzed cow's-milk-based formula. But Mead's argument fails to answer critical questions like: what role does it claim D.W.'s exposure to a hydrolyzed product played in his development of NEC? Is Mead claiming, without evidence, that hydrolyzed products mitigated against the risk of NEC? Is it contending, again without evidence, that the gap between his last hydrolyzed product feed and exposure to preterm formula somehow impacted the outcome for D.W.? Is it contending that exposure to hydrolyzed formula was a potential culprit in the onset of his NEC? Or is it arguing the cow's-milk contained in its hydrolyzed products is somehow magically different than the cow's-milk in its preterm infant formula? Mead's failure to answer any of these questions in its brief is important—if hydrolyzed products played no role in D.W.'s development of NEC, then nothing about D.W.'s nominal exposure to them bears on Dr. Spector's analysis.

II. Relevant Background

The PLC will not belabor Dr. Spector's qualifications and methodology, since Mead does not directly question them and, in any event, the Court has heard them *ad nauseum* in various briefs and hearings.

D.W. died of NEC after being fed exclusively CMBF for ten days. He was born on May 12, 2020, at 29 weeks and 4 days gestation. No. 1:22-cv-03737, ECF No. 53-9 (DeZure Rep.) at 5. He was started on enteral feeds of donor breastmilk on his first day of life. *Id.* at 5. D.W. had two feeds of 2 mL of donor breastmilk on May 13, 14, and 15. *Id.* On May 16, he was started on mother's own milk. *Id.* On May 19, fortifier was added to his feeds of mother's own milk. *Id.* He received Pregestimil and Nutramigen, formulas which contain hydrolyzed proteins, between May 25 through June 3, 2020. *Id.*

On June 3, D.W. was transitioned back to breastmilk and fortifier. *Id.* On June 6, he was started on CMBF Enfamil Premature Formula (EPF) mixed with breastmilk. *Id.* Three days later, on June 9, D.W. was given feeds of EPF High Protein formula only and then received mothers milk with HMF on June 10, 11, and 12. *Id.* D.W. was transitioned to exclusively EPF, which is not hydrolyzed, on June 13. *Id.* He developed poor tolerance of feeds on June 18, days after switching exclusively to formula feeds. *Id.* D.W. continued to decline through June 22, when his care team became concerned that he was septic. *Id.* at 5-6. An X-ray and laparotomy on June 22 determined that D.W. had NEC totalis. *Id.* at 6. He received compassionate care until he passed away on June 23. *Id.*

In other words, D.W. was given mixed feedings until June 13, when he was transitioned exclusively to formula:

May 12 -June 3	Mixed feedings of human milk, human milk with fortifier, and hydrolyzed CMBF.
June 3 – June 13	Mixed feedings of breastmilk and fortifier, and non-hydrolyzed formula-only.
June 13 – June 23	Exclusively CMBF formula

Over the course of his life, over 70% of D.W.'s feeds were formula:

Breast milk ²	29.72%
Pregestimil	8.86%
Nutramigen	14.14%
EPF	47.28
Total Formula Feeds	70.28%

In this case, D.W. stopped consuming Nutramigen or Pregestimil – which accounted for 23% of all his feeds – on June 3, nearly three weeks before he was diagnosed with NEC totalis and passed away. Dr. DeZure, Plaintiff's specific-causation expert, concluded within a reasonable degree of medical certainty that "it is more likely than not that if [D.W.] was not fed formula, or had been fed exclusive human milk or human milk based nutritional products, he would be alive today." *Id.* at 12.³

III. Law and Argument

a. Dr. Spector's opinion fits the facts and is helpful to the jury.

The *Daubert* inquiry requires the court to "determine whether the evidence or testimony assists the trier of fact in understanding the evidence." *Deimer v. Cincinnati Sub-Zero Prods., Inc.*, 58 F.3d 341,

² As noted above, D.W.'s doctors often fortified breastmilk with cow's-milk-based fortifier. For ease of calculation, the percentage of fortifier was not segregated from the breastmilk percentage. That said, because fortification typically represents 16% of each feed by volume, the actual total formula exposure is underreported by roughly 4.7% (meaning that even if one were to exclude the hydrolyzed products from D.W.'s total feeding history, he still consumed in excess of 50% CMBF over his life).

³ D.W.'s total exposure on a percentage basis throughout his entire life to a cow's-milk-based product was at least 70% (47.28% of which was exclusive CMBF, with 100% being fed over the final ten days of life). It should not be lost on the Court that a mere three weeks ago, Mead's Co-Defendant (Abbott) served a supplemental report ostensibly chock-full of peer-reviewed literature establishing exposure to $\geq 50\%$ of cow's-milk-based products suggests a dose response. ECF No. 693-2 (Amended Rep. of Dr. Makuch). Mead ignores that approach here, likely because D.W.'s "total feed" of formula was so high that it clearly fits within scores of articles Abbott relies on in its briefing in the *Brown* case. Instead, Mead pivots to an argument that epidemiology must exactly mirror a given individual's case to be reliable. Nothing in epidemiology supports that argument. That is particularly relevant here since individual feeding regimes differed within virtually every study in this litigation. *Infra* at 6-7. Mead is clearly aware of this fact but chose to ignore it.

344 (7th Cir. 1995). Expert testimony must “fit” the issue to which the expert is testifying and have a “valid scientific connection to the pertinent inquiry.” *Id.*; *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 580 (1993). “If the proposed expert testimony meets the *Daubert* threshold of relevance and reliability, the accuracy of the actual evidence is to be tested before the jury with the familiar tools of ‘vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.’” *Lapsley v. Xtek, Inc.*, 689 F.3d 802, 805 (7th Cir. 2012) (quoting *Daubert*, 509 U.S. at 596).

Dr. Spector’s opinion that exposure to preterm infant formula can cause NEC, with greater exposure increasing the risk, squarely fits the facts of this case—D.W. developed NEC after receiving mixed formula/fortifier feeds or exclusively preterm formula for nearly three weeks. Notably, he contracted NEC ten days after the switch from mixed feeds to a 100% formula diet—a fact that is consistent with Dr. Spector’s analysis. His analysis and methodology are relevant, reliable, and consistent, and his conclusions are helpful to the jury. Mead, understandably, did not care for the result of its failed attempt to exclude Dr. Spector. But its arguments here “raise matters of weight rather than admissibility.” Fed. R. Evid. 702, Adv. Comm. Notes, 2023 Amendments.

b. Dr. Spector’s opinion is as applicable to this case as it was to *Mar*.

Dr. Spector’s opinion that the risk of NEC increases with the amount of exposure to formula does not require any extrapolation to be applicable in *Inman*. D.W. received a combination of breastmilk and fortifier until June 13. After that, he received exclusively preterm formula until his death on June 23. During those ten days, he exhibited signs of NEC before passing away from NEC totalis. Mead does not cite a study that explicitly excludes infants because they received hydrolyzed formula at some point in their lives and has not argued that there is a systematic exclusion of these infants from the studies upon which Dr. Spector relies.

Most of the studies in this MDL included mixed-feeding regimes like those set forth here (*i.e.*, exposure to multiple forms of feeding and products). For example, Embleton (2023), included four

treatment centers.⁴ Two of those centers added probiotics to the child's diet—a supplement thought to reduce NEC.⁵ Similarly, Jensen (2023), allowed individual doctors to supplement the infant's diets with vitamins, nutrients, and fats “when needed,” meaning feeding regimes were not uniform across the study.⁶ Finally, in Corpeleijn (2016), the feeding protocols during Phase-II were wildly inconsistent, including feeds in the cow's-milk arm that ranged from no formula, to some formula, to all formula.⁷ Each of these studies established eligibility criteria based on the infant's weight and age—not the type (or, for that matter, the amount) of formula consumed. And notwithstanding the fact that individual feeding regimes varied (both in terms of content and food source), each was peer-reviewed and accepted for publication. As such, there is *no evidence* to suggest, let alone prove, that D.W. did not fit within the eligibility requirements for the vast majority of relevant studies—a point Mead's brief is wholly silent on.

Mead's arguments that D.W. would have been excluded from studies simply because during one eight-day period he received specialized formula is simply wrong. As noted above, eligibility requirements in these studies were typically based on weight and gestational age—not the product consumed. The rationale for this is simple: most, if not every study, measured growth and tolerance because it would be unethical to study whether exposure to Product A (or a combination of Product A and B) increased the risk of NEC. Mead knows this. Nonetheless, Defendants' (both Mead and Abbott) experts rely on these types of studies to support their contention that formula does not cause

⁴ Becker Decl., Ex. D, Embleton et al., *Effect of an Exclusive Human Milk Diet on the Gut Microbiome in Preterm Infants A Randomized Clinical Trial*, 6 JAMA Open 3 (March 2, 2023).

⁵ The study was accepted for peer-reviewed publication, notwithstanding the facts that it included a supplement thought to reduce the risk of NEC (artificially lowering NEC rates in the cow's-milk arm).

⁶ Becker Decl., Ex. E, Jensen et. al, *Effect of Human Milk-Based Fortification in Extremely Preterm Infants Fed Exclusively with Breast milk: a randomized controlled trial*, The Lancet (online publication) at 3 (2023).

⁷ Becker Decl., Ex. F, Corpeleijn et al., *Effect of Donor Milk on Severe Infections and Mortality in Very Low-Birth-Weight Infants*, 170 JAMA Pediatr. 7 (May 2, 2016).

NEC. That is because both Mead and Abbott know these types of minor deviations do not impact the general outcome for the overarching studied population—i.e., preterm infants exposed to CMBF.

Further, Mead’s argument assumes that D.W. would: 1) not have qualified for inclusion in the study’s original criteria (a significant stretch given the vast majority were growth studies); or 2) have been excluded upon being fed a cow’s-milk-based hydrolyzed product. But Mead offers no evidence or meaningful argument that such a protocol exists or that exposure to a mixed feeding regime required exclusion from the study. And, in fact, the peer-reviewed literature cited above evidences the exact opposite. The simple fact is that D.W. would have “fit” within virtually *every* study protocol in this case. Nothing in Mead’s brief suggests otherwise.

Equally problematic and ignored by Mead, this Court has repeatedly rejected Defendants “entire feed” argument in favor of the PLC’s contention that the proper timeframe to measure whether formula exposure is harmful is from the start of exposure to formula itself. ECF No. 639 (*Daubert* Hrg. Tr.) at 133:7-12; ECF No. 683, PageID #30046 (Order); ECF No. 685 (Court’s Minute Order, September 2, 2025). Mead’s argument requires the Court to conclude that exposure to a hydrolyzed cow’s-milk-based formula, which includes broken-down proteins is somehow not a CMBF. Given the products D.W. consumed during the early stages of his life are, in fact, cow’s-milk-based products, one is hard-pressed to understand how *any* of Mead’s arguments make logical sense.

Thus, the fact pattern here fits squarely within Dr. Spector’s opinion. A review of his report indicates that the studies he relied on involved human milk, milk with fortifier, and preterm formula. This was the feeding pattern for the last twenty days of D.W.’s six-week life. Prior feeding of hydrolyzed formulas does not negate the usefulness of Dr. Spector’s opinion that increased CMBF exposure increases the risk of NEC. The fact remains that when D.W. was exclusively fed preterm formula he developed fatal NEC.

c. General-causation experts are not required to delineate every potential fact pattern of every case in the MDL.

In *In re: TRT*, the court held that “[e]xperts’ general causation reports can hardly be expected to discuss the precise circumstances of each potential plaintiff’s injury. That would effectively erase the distinction between general and specific causation.” *In re TRT*, No. 14 C 1748, 2023 WL 7183216, at *4 (N.D. Ill. Nov. 1, 2023). It is inevitable that the feeding regimens of critically ill and vulnerable infants will vary considerably as their medical teams work to save their lives. This does not mean that every possible feeding permutation must be covered by a study upon which an expert relied, nor is it a reasonable expectation of general-causation experts to find a study applicable to each and every MDL plaintiff.

This is different than the situation in *Diggs*, where the Court found the “fit” question salient because infants of that plaintiff’s size and weight were “systematically” excluded from study populations. No. 1:22-cv-05356, ECF No.114, PageID #21831, n.7. Infants who were fed hydrolyzed protein products were not systematically excluded from the studies upon which Dr. Spector relied—and Mead offers no evidence to the contrary. To condition admissibility on a close examination of every feeding pattern of every study participant, no matter how untethered from the time frame in which they were fed human milk and preterm formula, is the kind of arbitrary boundary the Court found unacceptable with respect to the general-causation experts. This is not to say Mead is without recourse if it has concerns about the strength of the studies on which Dr. Spector relied or his conclusions—the proper way to challenge them is on cross-examination. *Boncher v. 3M Co.*, No. 5:24-CV-01403-JMG, 2025 WL 511116, at *8 (E.D. Pa. Feb. 14, 2025). Mead will have its chance to do that at trial.

d. The studies Dr. Spector relied on are applicable to babies like D.W.

Mead rests its entire argument on the fact that D.W. received hydrolyzed formulas and makes the conclusory assertion that “[n]one of the 29 studies on which Dr. Spector relies involve any infant

being fed hydrolyzed formulas.” No. 1:22-cv-03737, ECF No. 53 at 5. But Mead only discusses two studies and then assumes D.W. would have been excluded based on his feeding pattern. Mead does not cite a single study criterion that specifically excludes infants who received hydrolyzed protein products at any point during their lives, or differentiate between hydrolyzed and non-hydrolyzed formulas.

Mead’s argument is misguided. For example, Mead insists that D.W. would have been excluded from Sullivan because for eight days prior to his transition back to breastmilk and fortifier (followed by ten days of exclusively preterm formula), he received hydrolyzed formula. At the outset, as set forth in Table IV, Sullivan measured infants exposed to formula at significantly different time intervals. No. 1:22-cv-03737, ECF No. 53-7 (Sullivan et al. (2010)). Specifically, some infants in the bovine arm started on formula weeks after their first feed. There is no discussion of what the infant received prior to exposure. More relevant than that, Sullivan’s inclusion criteria were that the infants were born at a certain weight, during a certain gestational age and switched to a cow’s-milk based product at some point in their feeding protocol. *Id.* That is exactly what happened here. Even if the exposure to a hydrolyzed product were relevant, and it is not, D.W. falls squarely within the Sullivan protocol since he fell within the applicable weight and gestational age, and transitioned to CMBF during the last 20 days of life.

The appropriate window of time to determine whether the studies are applicable to D.W. is not from day one of life, as Mead would have it. The window of time properly begins when he was fed human milk products and preterm formula. The Court summed up the issue this way at oral argument on general-causation experts:

If I’ve never eaten blueberries before in my life and I eat blueberries and I suddenly get hives, the doctor says, you know, “you may have been having some kind of allergic reaction.” He wouldn’t say, “okay, but blueberries constitute .01 percent of the things you’ve eaten over your whole life, so it couldn’t be that.”

ECF No. 639 (*Daubert* Hrg. Tr.) at 133:7–12. Just like cancer risk from cigarettes is measured from the start of cigarette use (i.e., pack years), exposure to formula can be measured only from when an infant is first fed formula. Until the toxin is introduced, there is nothing to measure. Dr. Spector’s opinion that risk of NEC rises commensurate with the consumption of CMBF fits the facts of this case: D.W. received human milk or human milk and fortifier in the ten days before his exposure to Enfamil Premature High Protein formula. In his last ten days of life—the period encompassing the onset of NEC symptoms—he received exclusively preterm formula.

Mead also attempts to make hay from Dr. Spector’s unfamiliarity with hydrolyzed proteins in general. No. 1:22-cv-03737, ECF No. 53 at 2 (“Dr. Spector is unfamiliar with these types of formulas, having no idea what ingredients they contain...”). Mead cites no authority for the proposition that he must be familiar with the intricacies of formula ingredients to offer an opinion on pediatric epidemiology—his exact area of expertise. The Court has spoken on this issue as well, relying on *In re: Zimmer*, where the court “allowed the expert to testify to conclusions ‘based on his epidemiological and general clinical research expertise’” even though he did not specialize in knee surgeries. ECF No. 646, PageID #29129. The Court found “Dr. Spector’s experience in epidemiological research qualifies him to review and interpret the findings of epidemiological research in this case.” ECF No. 646, PageID #29129. The same is true here. He does not need to be familiar with the composition of every product on the market to offer an epidemiological opinion.

e. Mead should not be allowed to continue making the same argument.

Mead’s argument is derivative of Abbott’s argument regarding whether a general-causation expert must evaluate the overall feeding history for each individual infant versus evaluating only the time the infant was exposed to formula. The Court has twice rejected this argument. Undeterred, Mead returns for a fourth attempt to exclude Dr. Spector based on facts “unique” to a D.W. contending those facts (detached as it may be from Dr. Spector’s general causation opinion) require

exclusion. But Defendants are not permitted to endlessly re-litigate an issue simply because they were unsuccessful the first time. *Parklane Hosiery Co. v. Shore*, 439 U.S. 322, 326 (1979). Collateral estoppel is appropriate where: (1) the issue in the current proceeding is identical to the prior one; (2) the issue in the prior proceeding was actually litigated and decided; (3) defendants had a full and fair opportunity to litigate the issue; and (4) the issue previously litigated was necessary to the outcome of the prior case. *Bifolck v. Philip Morris USA Inc.*, 936 F.3d 74, 79–80 (2d Cir. 2019); *In re E. I. du Pont de Nemours & Co. C-8 Pers. Inj. Litig.*, 54 F.4th 912, 923–26 (6th Cir. 2022).

i. The first prong concerns issues, not claims or causes of action.

The first prong “is concerned not with claims or causes of action as a whole, but with *issues*—single, certain, and material points arising out of the allegations and contentions of the parties.” *Bifolck*, 936 F.3d at 81 (cleaned up) (emphasis in original). This issue—the single, certain, and material point of whether Dr. Spector was required to base his opinions on studies that include each individual fact pattern in the MDL—arose in Mead’s argument to exclude Dr. Spector generally from the MDL. Mead argues that Dr. Spector’s opinions are unhelpful to the jury because “[n]one of the 29 studies on which Dr. Spector relies involve any infant being fed any of the nonstandard, hydrolyzed formulas like the ones [D.W.] received.” No. 1:22-cv-03737, ECF No. 53 at 5. It is difficult to identify what underpins that conclusory statement, since Mead only describes two studies in detail. On its own terms, Mead’s motion only claims that infants with D.W.’s feeding regimen would “*likely* have been excluded from every study underlying Dr. Spector’s report because there was more than a week-long period when he was unable to receive either human milk or preterm formula.” *Id.* at 1 (emphasis added). This is the same argument Mead made months ago, in response to which the Court held that the studies informing his opinion were not limited to infants weighing less than 1500 grams. According to the Court, “Dr. Spector’s broad analysis of studies exploring a range of different feeding mixtures (see *supra* n. 8) applies across the diverse feeding methods in the MDL cases.” ECF No. 646, PageID

#29131. Mead's current argument is the same one it made and lost, just repackaged with different words.

ii. The second and third prongs are met, since the issue was fully briefed and extensively litigated.

This issue was fully briefed and extensively litigated in a day-long hearing in this MDL. Mead fully participated in both the briefing and the hearing. Following a complete airing of the issue, the Court issued an order rejecting the argument Mead makes in the present motion. ECF No. 646, PageID #29150. This factor protects against unfairness by “ensuring that the issue was really disputed and that the loser... put out his best efforts.” *Bjfolck*, 936 F.3d at 82 (cleaned up). Mead has given no indication since this issue was fully briefed, argued, and decided months ago that it does not believe it had the opportunity to fully litigate it. Nor could it. There are filed briefs and a hearing transcript to indicate otherwise.

iii. The fourth prong is satisfied, since the question of admissibility under *Daubert* was necessary to the outcome of the case.

Daubert determinations often govern the disposition of cases such as this, which require expert testimony. Dr. Spector's general-causation opinion also served as a basis for the opinions of Plaintiffs' other general-causation expert, Dr. Jennifer Sucre. If Dr. Spector's general-causation opinion is excluded, as Mead contends it should be, then Plaintiffs would no longer have a general-causation expert to offer. This issue is not only necessary, but potentially case-dispositive. The fourth prong is satisfied.

iv. Holding Mead to this Court's prior ruling and avoiding needlessly rehashing the same issues is not unfair to Mead.

There is no procedural or substantive argument available to Mead now that was not available to it in its initial Rule 702 briefing or oral argument in March. Defendants' repeated attempts to seize on the narrowest differences in the fact patterns of each plaintiff to exclude general-causation experts on “fit” grounds must stop. It is a waste of the Court's and the parties' resources to re-litigate this

specific issue with every trial. Taken to its logical conclusion, it would mean that no plaintiff could possibly be representative since it is unlikely that any two infants had identical experiences to each other, let alone that studies relied on by the general-causation expert envision and explicitly include every idiosyncrasy present in the treatment of critically ill infants. This is simply a motion to reconsider by another name, and an untimely one. The Court should not continue to entertain it.

f. Mead's arguments as to Dr. DeZure's opinions are misplaced here.

Mead presents Dr. DeZure's opinion here as solely related to caloric density. Plaintiff will argue the specifics as to Dr. DeZure in briefing on the relevant motion, which is not this one. This argument is irrelevant to the admissibility of Dr. Spector's opinion that CMBF causes NEC in premature and low-birth-weight infants.

g. If D.W.'s feeding schedule was so unique that no study could encompass it, this is not a representative case.

MDLs are intended to "promote the just and efficient conduct" of consolidated proceedings. 28 U.S.C.A. § 1407 (West). Bellwether trial picks must be representative of the MDL as a whole to advance that objective. This makes sense, since the goal of a bellwether trial is to "garner information useful for the parties to evaluate the strengths and weaknesses of their arguments and evidence as well as to assess the risks and costs of litigation." *In re Hair Relaxer Mktg. Sales Pracs. & Prods. Liab. Litig.*, No. 23-CV-0818, 2025 WL 354410, at *1 (N.D. Ill. Jan. 31, 2025). In order to garner that information, "the results of the bellwether trials must be reasonably representative of all the cases in the MDL." *Id.*

The bellwether selection protocol in this case required the parties to "select cases that they have a good faith belief are representative of the body of then-filed cases as a whole, and that should be subject to discovery and then taken to trial." ECF No. 210 (Amended CMO7), PageID #2636. Mead had a PFS, medical authorizations, medical records (including D.W.'s feeding regimen), and the deposition of D.W.'s mother long before choosing this case as its sole trial pick. *Id.* Its own admission

that D.W.'s case is "unique" begs the question of whether Mead was acting in good faith when it picked this case. A plaintiff whose specific facts are so out of the ordinary that they are "not compatible with a study protocol" is non-representative and does not advance the goals of multi-district litigation. If an expert's opinion is subject to exclusion based on a plaintiff's particular circumstances, then the case does nothing to advance the resolution of the remaining cases, where plaintiffs are not subject to the same circumstances. If indeed D.W.'s particulars are such that he would effectively be excluded not only from any litigation but also from any study, as Mead claims, he is not representative.⁸ Yet, Mead chose this case as its sole trial pick.

Mead cannot be allowed to argue that general-causation experts must base opinions on studies so specific that they cover every conceivable fact pattern in an MDL while at the same time choosing outlier bellwether trial picks with "unique" circumstances and demanding exclusion of experts for failure to locate a study with sufficient specificity to that outlier. This would undermine the very efficiency MDLs are designed to promote. The Court should not entertain it.

IV. Conclusion

Plaintiffs have repeatedly demonstrated that Dr. Spector's opinions are admissible by a preponderance of the evidence. His opinions are reliable and well-supported by literature and case law, and will help the jury understand the causal relationship between Mead's cow's-milk-based products and NEC, easily clearing the Rule 702 bar. His opinions fit the facts of this case and should be presented to the jury. Mead's motion should be denied.

⁸ Plaintiffs do not concede that D.W.'s circumstances are unique but simply point out that if Mead thinks they are so unique that a general causation expert must be excluded, it may not have made the best choice of representative bellwether trial picks.

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Respectfully submitted,

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